Special 510(k) Submission K071921 3rd Response

Innovasis Inc.
Innovasis Excella® Spinal System.

510(k) Summary

August 7, 2007

NOV 1 6 2007

Company: Innovasis Inc.
614 East 3900 South
Salt Lake City, UT 84107

Contact: Warren M. Dansie
Phone: (801) 261-2236
Fax: (801) 261-0573

Trade Name: Excella® Spinal system

Common Name: Rod and Screw Spinal Instrumentation

Classification: Product Codes: KWP, KWQ, MNI, MNH, NKB
Regulation Numbers: 21 CRF 888.3050, 888.3060, 888.3070
Classification Names:
Spinal Intervertebral Body Fixation Orthosis.
Spinal Interlaminal Fixation Orthosis
Spondylolisthesis Spinal Fixation Device System
Pedicle Screw Spinal System
Panel code: 87

Substantially Equivalent Devices:
- K042143 – Excella-M® - Innovasis
- K974749 – Synergy VLS™ Open – Interpore Cross
- K022623 – Moss Miami™ - Depuy
- K050461 – Xia™ - Stryker
- K022191 – Tenor™- Medtronic

Predicate Device Description:

The Excella®-M Spinal System consists of 6AL-4V Titanium alloy implants meant to be used in a system. The monoaxial bone screws are offered in a variety of different lengths ranging from 30mm to 60mm as well as the following diameters, 5.5mm, 6.5mm and 7.5mm. The bone thread portion of the screws features a self-tapping, double lead thread, to reduce the number of revolutions for insertion. Locking screws include a buttress thread design for axial strength and to prevent screw loosening. The system uses 6mm Titanium rods, which are placed in the head of the screws and the system is locked in place with Titanium locking screws to grip the 6mm rods. The Cross Links consist of three components and are constructed to stabilize the relation between two rods.

Modified Device Description:

The Excella® Spinal System broadens to include the Excella®-P bone screws, which feature a multi-axial joint for free motion of the screw head to allow the physician greater flexibility when placing the screws, and a series of 4.5mm diameter polyaxial bone screws of 30mm, 35mm, 40mm and 45mm lengths. The locking caps for Excella®-P are a two piece design which includes a threaded locking screw attached to an alignment cap. The alignment cap is attached to the bottom of the locking screw and rotates about the radial axis. The modified cross connectors come in various pre-assembled, adjustable lengths and allow for variation in vertical placement on two rods.

Technological Comparison:
The implants are machined from the same Medical Grade Titanium (6AL-4V) per ASTM 136-02. Performance testing per ASTM F1717 for Static Compression Bend, Static Torsion and Dynamic Compression has demonstrated that the Excella-P® Spinal System is substantially equivalent to the predicate devices. The intended use of the Excella®-P device is the same as the predicate Excella®-M device, thus the Excella® System includes both the Excella®-M device and the Excella®-P device.

Indications for use are as follows:

The INNOVASIS 'Excella®' Spinal System, when used for pedicle screw fixation is intended only for patients:

a) Having severe spondylolisthesis (Grade 3 & 4) at the L5-S1 joint;
b) Who are receiving fusion using autogenous bone graft only;
c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
d) Who are having the device removed after the development of a solid fusion mass.

The INNOVASIS 'Excella®' Spinal System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic deformities of the thoracic, lumbar, and sacral spine:

a) Degenerative spondylolisthesis with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Previous failed fusion (pseudoarthrosis).

The INNOVASIS 'Excella®' Spinal System, when used for anterolateral non-pedicle fixation, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spinal stenosis;
c) Spondylolisthesis;
d) Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis);
e) Pseudoarthrosis;
f) Tumor;
g) Trauma (i.e. fracture or dislocation); and
h) Previous failed fusion.

The INNOVASIS 'Excella®' Spinal System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (defined as back pain of disogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spinal stenosis; c) Spondylolisthesis;
d) Spinal deformities (i.e. scoliosis, kyphosis and/or lordosis);
e) Pseudoarthrosis;
f) Tumor;
g) Trauma (i.e. fracture or dislocation);
h) Previous failed fusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

Innovasis, Inc
% Mr. Warren Dansie
614 East 3900 South
Salt Lake City, Utah 84107

Re: K071921
Trade/Device Name: Innovasis Excella® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class III
Product Codes: NKB, KWP, MNI, MNH
Dated: October 21, 2007
Received: November 1, 2007

Dear Mr Dansie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Fuchs for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071921

Device Name: Excella-P

Indications For Use:

The INNOVASIS 'Excella™' Spinal System, when used for pedicle screw fixation is intended only for patients:
a) Having severe spondylolisthesis (Grade 3 & 4) at the L5-S1 joint;
b) Who are receiving fusion using autogenous bone graft only;
c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below);
and
d) Who are having the device removed after the development of a solid fusion mass.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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(continued from Page 1)

The INNOVASIS 'Excella™' Spinal System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic deformities of the thoracic, lumbar, and sacral spine:

a) Degenerative spondylolisthesis with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Previous failed fusion (pseudarthrosis).

The INNOVASIS 'Excella™' Spinal System, when used for anterolateral non-pedicle fixation, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spinal stenosis;
c) Spondylolisthesis;
d) Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis);
e) Pseudoarthrosis;
f) Tumor;
g) Trauma (i.e. fracture or dislocation); and
h) Previous failed fusion.

The INNOVASIS 'Excella™' Spinal System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (defined as back pain of disogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spinal stenosis; c) Spondylolisthesis;
d) Spinal deformities (i.e. scoliosis, kyphosis and/or lordosis);
e) Pseudoarthrosis;
f) Tumor;
g) Trauma (i.e. fracture or dislocation);
h) Previous failed fusion.

Barbara Bonenup

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071921